FOOD MARKETING INSTITUTE

655 15th Street, N.W.
Washington, DC 20005-5701
Tel: (202) 452-8444
Fax: (202) 429-4519
E-mail: fmi@fmi.org
Web site: www.fmi.org

April 24, 2000

Via Messenger

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: FDA Draft Study Report on Feasibility of Appropriate Methods of Informing Customers of the Contents of Bottled Water (Docket No. 97N-0436)

Dear Sir or Madam:

The Food Marketing Institute (FMI) is pleased to respond to the Food and Drug Administration's (FDA's) request for comments on the Agency's draft study report on the feasibility of appropriate methods of informing customers of the contents of bottled water. 65 Fed. Reg. 8718 (Feb. 22, 2000). We agree with FDA's assessment of the feasibility of the methods outlined. In particular, as explained more fully below, we agree that point of sale pamphlets are not a feasible means of providing consumers with information about bottled water. Of course, even if the Agency concludes that a method is feasible, FDA must still determine whether requiring additional information is necessary, desirable or within the Agency's statutory authority. FDA has stated, however, that these issues are beyond the scope of the present inquiry and, therefore, that FDA will not consider these matters at this time. Accordingly, we have limited our comments to the feasibility issue presented by the Agency.

FMI is a non-profit association that conducts programs in research, education, industry relations and public affairs on behalf of its 1,500 members and their subsidiaries. Our membership includes food retailers and wholesalers, as well as their customers, in the United States and around the world. FMI's domestic member companies operate approximately 21,000 retail food stores with a combined annual sales volume of $300 billion, which accounts for more than half of all grocery sales in the United States. FMI's retail membership is composed of large multi-store chains, small regional firms, and independent supermarkets. Our international membership includes 200 members from 60 countries.

The Safe Drinking Water Act (SDWA) Amendments required the Environmental Protection Agency (EPA) to issue regulations mandating community water systems to provide every customer with an annual "consumer confidence report" (CCR) on the level of contaminants in the drinking water purveyed by the system. § 114(a). In addition, the law required FDA to publish a draft study on the feasibility of appropriate methods, if any, of informing customers of the contents of bottled water. § 114(b). Toward this end, in November, 1997, FDA requested comments on several matters relevant to the issue, including the type of information analogous to the extensive CCR that might be provided to consumers on bottled water through various different mechanisms. 62 Fed. Reg. 60721 (Nov. 12, 1997). Based on the information received, FDA prepared and published the draft study report of interest here. 65 Fed. Reg. at 8718. The study report evaluates the feasibility of several possible methods of providing information to consumers, including on labels and in point of purchase pamphlets.

We agree with FDA's analysis concerning the impracticality of providing additional information to consumers through labeling. 65 Fed. Reg. at 8720. First, the information under consideration has the potential to change frequently. Therefore, the corresponding label changes could be extremely costly, particularly for smaller manufacturers. Moreover, if as a result of the level changes, the bottled water bore a label that was no longer accurate, the product would be considered misbranded and, therefore, subject to seizure and condemnation under the Federal Food, Drug, and Cosmetic Act.

Second, the CCR required by the SDWA includes extensive information that is not relevant to bottled water. Given the small surface area of bottled water labels and the amount of information that must already be contained on the label, adding an extensive amount of information would be problematic. As neither the draft study nor the SDWA Amendments indicate that additional labeling is necessary for safety reasons, cluttering the label with unnecessary information will serve no useful purpose and may deter people from attending to truly important safety-related labeling.

FDA used a similar analysis to conclude that requiring point of sale pamphlets would not be feasible. 65 Fed. Reg. at 8721. Specifically, the information printed on a pamphlet would be subject to the same frequent changes, and therefore, costs, that would be associated with labeling. Moreover, providing pamphlets at retail presents additional practical concerns. Although our members are willing to assist the Agency in public education campaigns and have done so individually and through FMI's auspices on many occasions, we question the wisdom and practicality of such an undertaking in this instance. For example, a substantial burden would be placed on retailers to assure that the pamphlets were consistently available to consumers. Furthermore, if each different size of each different manufacturers' product was required to have a pamphlet associated with it, retailers would need to establish a virtual library in their stores to ensure adequate space for the bottled water and their accompanying literature. It would be unfair to ask retailers to bear this extraordinary burden, especially since the utility of such information

has not even determined. Accordingly, we agree with FDA's conclusion that providing information to consumers on bottled water through point of sale pamphlets is not feasible.

We appreciate the opportunity to provide comments on this important matter. If we may be of assistance in any way, please do not hesitate to call on us.

Sincerely,

Tim Hammonds
President and CEO

FOOD MARKETING INSTITUTE
655 15th Street, N.W.
Washington, DC 20005-5701

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, M 20852